

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Effectiveness of the gluten free diet and gluten containing diet on gastrointestinal and behavioral indices for children with Autism Spectrum Disorders

#### Protocol summary

##### Summary

In this study, 80 children diagnosed with Autism spectrum Disorders attending the rehabilitation center for children with ASD are going to be studied. The aim of this study is to determine the effect of gluten free diet intervention on ASD and gastrointestinal symptoms. Inclusion criteria consist of: patients diagnosed with ASD, age between 4-16 years, also the exclusion criteria are: healthy children not diagnosed with ASD and unwilling to participate in the study. Participants will be divided into two groups of 40. One group will be achieving 200 g gluten free grains and the second group will receive 200 g grains containing gluten in the duration of 6 weeks intervention. At the baseline and at the end of the study a demographic questionnaire, GARS-2 and a questionnaire for evaluating gastrointestinal symptoms will be completed by interviewing parents. Also anthropometric measures including weight, height and BMI will be calculated and assessed. Additionally 5 ml blood sample will be taken after a night fasting by a laboratory technician at the rehabilitation center for children with ASD, in the beginning and at the end of the intervention. The blood samples will be centrifuged and stored at -80° C. Anti-tissue transglutaminase IgA antibodies (tTGA) will be analyzed by chemiluminescence immunoassay system and total serum IgA levels will be analyzed by nephrometry scoring system.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201404212017N20**  
Registration date: **2014-05-27, 1393/03/06**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-05-27, 1393/03/06

##### Registrant information

###### Name

Alireza Ostadrahimi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1335 7580

###### Email address

ostadrahimi@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-05-22, 1393/03/01

##### Expected recruitment end date

2014-08-23, 1393/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of the gluten free diet and gluten containing diet on gastrointestinal and behavioral indices for children with Autism Spectrum Disorders

##### Public title

The effect of gluten free diet on gastrointestinal and behavioral indices in children with ASD

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: patients diagnosed with ASD ; age between 4-16 years; capable of eating food; willing to participate in the study Exclusion criteria: children without ASD; pursuing a particular diet; unwilling to participate in the study

## Age

From **4 years** old to **16 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University of Medical Sciences

##### Street address

Attar Alley, Golgasht Street, Tabriz University of Medical Sciences, Tabriz, Iran

##### City

Tabriz

##### Postal code

#### Approval date

2014-04-14, 1393/01/25

#### Ethics committee reference number

937

## Health conditions studied

### 1

#### Description of health condition studied

Childhood Autism

#### ICD-10 code

F84.0

#### ICD-10 code description

Childhood Autism

## Primary outcomes

### 1

#### Description

Behavioural Symptoms

#### Timepoint

Before and After 6 Weeks Intervention

#### Method of measurement

Gilliam Autism Rating Scale Questionnaire

### 2

#### Description

Gastrointestinal Symptoms

#### Timepoint

Before and After 6 Weeks of Intervention

#### Method of measurement

Shahid Beheshti Questionnaire for Gastrointestinal Symptoms

### 3

#### Description

Tissue Transglutaminase Immunoglobulin A

#### Timepoint

Before and after 6 weeks of intervention

#### Method of measurement

Chemiluminescence Immunoassay System

### 4

#### Description

Immunoglobulin A

#### Timepoint

Before and after 6 weeks of intervention

#### Method of measurement

Nephrometry

## Secondary outcomes

### 1

#### Description

Body Mass Index

#### Timepoint

Before and after 6 weeks of intervention

#### Method of measurement

Weight/Height\*2

## Intervention groups

### 1

#### Description

Gluten Free Diet: Gluten free bread, biscuit, pasta

#### Category

Lifestyle

## 2

### Description

Gluten containing diet: Regular bread, biscuit, pasta

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Specialized treatment and rehabilitation center for children with pervasive developmental disorder

##### Full name of responsible person

Faezeh Ghalichi

##### Street address

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Bahram Poor gaseme Gargari

##### Street address

Attar Alley, Golgasht Street, Tabriz University of Medical Sciences, Tabriz, Iran

##### City

Tabriz

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Tabriz University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

*empty*

##### Domestic or foreign origin

*empty*

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Alireza Ostadrahimi

##### Position

PHD in Nutrition Sciences

##### Other areas of specialty/work

##### Street address

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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Faezeh Ghalichi

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MSc student in nutrition sciences

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##### Web page address

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*